# Guidelines for Modifications to a Consortium Organizational Roster

Modifications to a Consortium’s organizational roster must be requested in writing from the Consortium Lead Organization (CLO) Principal Investigator (PI) and approved by the Division of Cancer Prevention (DCP) Consortia Contracting Officer’s Representative (COR) and the DCP Associate Director for Clinical Research.

Consortium modifications include:

* Adding a participating organization (PO)
* Removing a PO

## I. Adding a Participating Organization

An institution may be added to a Consortium’s roster as a PO at the request of the CLO PI after approval from the DCP COR and Associate Director for Clinical Research.

The request must be submitted in writing via the DCP Protocol Information Office (PIO) to the DCP COR and Associate Director for Clinical Research independent of the Task Order RFP (TO-RFP) review cycle. Proposed POs should *not* be included as performance sites in a TO-RFP’s proposed organizational roster without prior DCP approval.

A. The following documentation must be submitted to the PIO.

1. A written request from the CLO PI to add the institution as a PO.
2. A description of the proposed PO’s potential contributions to the CLO in successfully conducting clinical trials within the DCP Early Phase Prevention Trials Program.

This should include a description of:

* the clinical skills and expertise of the investigator(s) and other staff in completing multi-institutional clinical trials,
* the access to and ability to accrue appropriate/targeted populations,
* the laboratory and staff resources to support translational research and correlative studies,
* an institution’s “track record” in participating in clinical trials research (i.e. timely accrual to clinical trials, few deficiencies noted during site monitoring visits, etc.).

1. A letter of commitment from the proposed PO’s investigator(s) stating the willingness to participate in the Consortium.
2. A CV or biosketch of the proposed PO investigator(s).

B. The request will be reviewed by the DCP COR and Associate Director for Clinical Research

The following criteria will be considered during this review:

* Based on its “track record”, will the proposed PO complement and/or expand the capabilities of the Consortium?
* Are the facilities and staff qualifications adequate and appropriate to support the Consortium’s objectives?
* Does the proposed PO have access to relevant study populations and experience in participant recruitment and retention in clinical trials?
* Are there concerns regarding the proposed PO’s ability to participate effectively in multi-center clinical trials?
* Are there other criteria specific to the proposed PO and the Consortium that should be evaluated prior to final approval, e.g. competing commitments to other clinical trials groups, or competing trials?

Approval of the PO does *not* constitute approval of additional funds for specific task orders. If funds are required for a new site to accrue to a specific trial, a revised budget request must be submitted to the Contracting Officer, COR, and study Scientific/Medical Monitors.

C. The decision about adding thePO will be sent in a letter from the PIO via e-mail. The CLO will receive one of the following two responses:

* 1. PO Approved

A Contact Data Form must be submitted to the PIO for each new PO.

If the PO will participate in a specific clinical trial (new or ongoing), then the CLO must collect and submit all required regulatory and administrative documents for the PO.

* 1. PO Disapproved

The reason(s) for not approving the PO will be documented in an e-mail to the CLO PI.

The CLO may be given the opportunity to address the problem areas and resubmit the request. A resubmission due date (and the appropriate documentation) will be specified in the email. All resubmitted requests must be sent to the COR and the Associate Director for Clinical Research via the PIO.

Resubmitted requests will be subject to the same review process as the original submission.

### II. Removing a Participating Organization

A PO may be removed from a CLO roster at the discretion of the CLO PI or as required by DCP.

A. The CLO PI should provide written notification to the COR via the PIO of the intent to remove a PO from the roster. This notice must include:

* the reasons for removing the organization and the effective date.
* a detailed description of the current status of the work performed by the PO (e.g., PO participated in [*study name*] but did not accrue any participants, or PO accrued [*x number of*] participants to [*study name*]. All participants are off study, a study closeout visit has been performed, and local IRB notified of study closure, or a transition plan outlining the management of outstanding PO administrative and/or protocol-specific activities is attached.)
* a description the CLO’s plans for compensating for the loss of the PO’s contribution to the Consortium.

The COR will send an email to the CLO PI with a copy to the PIO, acknowledging the CLO roster change. The CLO roster will be updated by the PIO.

* 1. DCP may choose to remove a PO from a Consortium roster if the institution fails to meet the performance requirements specified in the contract. This may include but not be limited to non-compliance with regulatory requirements, data and safety monitoring guidelines, participation in competing studies, and/or competing commitments to other clinical trials groups.